MAY 25 2006

K061305

510(K) Summary of Safety and Effectiveness

As required by 807.92

DEVICE ESTABLISHMENT AND CONTACT PERSON

Phil Chen
CHILIN TECHNOLOGY CO. LTD
No.71, Te Lun Road, Jen Te Hsian, Tainan County 717, Taiwan, R.O.C.
Ph: +886-6-279 - 4113 ext. 533
Facsimile: +886-6-249 – 4751

DATE SUMMARY PREPARED

14 December 2005

DEVICE NAME

Trade Name: 1.3MP Medical Color Reference Display, MDC1900-1LG, MDC1900-1LR
Common Name: Color LCD Monitor, Color Diagnostic Display, etc.
Classification Name: System, Image Processing, Radiological (CLASS II CFR 892.2050)

PREDICATE DEVICE

RadiForce R12 19" Class Color LCD Monitor by EIZO NANAO CORPORATION (K040982)

DEVICE DESCRIPTION

1.3MP Medical Color Reference Display, MDC1900-1LG (1LR) is a 19" color LCD monitor that displays image for medical use. It provides 1.3 mega pixel (1280 x 1024/1024 x 1280) resolution and enable the user to define desired DICOM GSDF Gamma settings such as 1.8, 2.0, 2.2 and 2.4 for more precise diagnose use in CT, MRI, HIS and PACS. This device is not suitable for a digital mammography system.

DEVICE OF INTEND USE

1.3MP Medical Color Reference Display, MDC1900-1LG (1LR) is intended to use in displaying images for review and analysis by trained medical practitioner for diagnose in CT, MRI, HIS and PACS. This device is not suitable for a digital mammography system.

CONCLUSION

1.3MP Medical Color Reference Display, MDC1900-1LG (1LR) has the same intended use as the predicate device R12, and they both share the similar characteristics except some minor differences which do not raise new questions of safety and effectiveness. The device does not contact with the patient nor does it control any life sustaining device. Therefore we concluded that it is substantially equivalent to R12 by EIZO NANAO CORPORATION (K040982).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2006

Chilin Technology Co., LTD
% Mr. Marc M. Mouser
Senior Project Engineer, Program Reviewer
Underwriters Laboratories, Inc.
2600 N.W Lake Road
CAMAS WA 98607-8542

Re: K061305
Trade/Device Name: Medical Display, MDC1900-1LG (1LR)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 27, 2006
Received: May 10, 2006

Dear Mr. Mouser:

This letter corrects our substantially equivalent letter of May 25, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Medical Display, MDC1900-1LG (1LR)

Indications For Use: 1.3MP Medical Color Reference Display, MDC1900-1LG, MDC1900-1LR is intended to use in displaying images for review and analysis by trained medical practitioner for diagnose in CT, MRI, HIS and PACS. This device is not suitable for a digital mammography system.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061305